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PEREGRINO FERREIRA et al. S.N. 09/331,261 JUN 02 2000

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Responsive to the formal rejection of claim 3, that claim is rewritten herewith as new claim 4. Support for this rewritten version of the claim is found at the bottom of page 6 and at the top of page 7 of the specification.

However, if the Examiner cannot approve the form of new claim 4, and if the application is otherwise in condition for allowance, the Examiner is authorized to cancel claim 4 by an Examiner's Amendment, so as not to impede allowance of the application as a whole.

Reconsideration is respectfully requested, for the rejection of the claims under 35 USC §103(a) as being unpatentable over PETERSON et al. 5,427,907, REIS et al., 1996 GenBank Acc. No. U53453 and BALL et al. ("Detailed Mapping of the Antigenicity of the Surface Unit Glycoprotein of Equine Infectious Anemia Virus by Using Synthetic Peptide Strategies", Journal of Virology, 1992, Vol. 66, pages 732-742).

PETERSON et al. relates to "synthetic peptide as antigen in an immunoassay...". Moreover, "The synthetic peptide corresponds to the amino acid sequence of an antigenic portion of GP-45 envelope protein of the equine infectious anemia virus" (Abstract). When the peptide amino acid sequences (25 amino acid) is searched in GENBANK, the blast result showed a related ENV polyprotein precursor (coat polyprotein) which contains both the amino acid sequences of coat protein GP90 and coat protein GP45.

BALL et al. describes the use of synthetic peptide to map antigenicity of gp90 "and also provide a potential peptide substrate for diagnostic assays." The peptide has different reactivity depending on its length as shown in Table 1 for monoclonal antibodies. In addition, the sequence of EIAV gp90 synthetic peptides (Figure 1) shows different immune horse reactivity, in a range of 10% to 100% (page 735-737), as well as different reaction with a panel of immune horse serum "indicating the presence of multiple immunogenic fragments".

The nucleic acid deposit in GENBANK (REIS et al., 1996) codes for a fraction of the full length protein used in the present application 09/331,261. The GENBANK nucleic acid sequence deposit predicted two additional His amino acids in the N-terminal and divergency of the other 38 amino acids, when compared to other GENBANK deposit sequences. This sequence is close in length (38 aa(aa=amino acids)) when compared to the peptides used in PETERSON et al. (25 aa) and BALL et al. (15-35 aa).

Furthermore, PETERSON et al. does not support the claim rejection, since the protein domain or immune dominant region is not the same. Furthermore, the proposed amino acid length is a peptide, as well as the one described by BALL et al. and the predicted amino acid sequence from deposit in GENBANK (REIS et al., 1996). The use of peptides as antigens is designed to "identify specific linear sites which are immunogenic in the native protein antigen" (BALL et al., page 738). "The particular conformational properties of the

peptide antigen may vary from the native protein structure and thus reduce antibody binding" (BALL et al., page 738).

This means that, for sensitivity, specificity and identification of an antigen, it is necessary to consider the full length protein to which the peptide can be used as a complement, particularly in retrovirus immunoassay. That is why "results of several studies have indicated that the recognition of peptide antigens by sera of HIV-1-infected individuals vary among the infected population during the course of infection in particular person" (BALL et al., page 738). In addition, BALL et al. points out that "a limitation of this study, however, is that the use of synthetic peptides cannot identify discontinuous conformation-dependent epitopes that may in fact represent important antigenic determinants of EIA gp90".

In conclusion, the invention relates to a non-glycosylated recombinant protein (rgp90) in immunoenzymatic assays, with no need of glycosylation, for identification of antibodies against the gp90 native surface protein of the EIA virus. In other words, the conformational structure of recombinant protein, without sugar, is enough to react with immunesera derived from infected horses; and since it is a full length protein, it will avoid the presence of major histocompatibility complex polymorphism observed in outbred populations. Accordingly, the present claims define a patentable invention that is non-obvious in view of the above documents.

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In view of the present amendment and the foregoing remarks, therefore, it is believed that this application has been placed in condition for allowance, and reconsideration and allowance are respectfully requested.

Respectfully submitted,

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By

A handwritten signature in black ink, appearing to read "Robert J. Patch".

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